Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A scalable continuous process for preparing nucleic acid-containing microparticles, the process comprising:

(a) providing a mixing chamber and a solvent removal device;

(b) continuously supplying a first emulsion to the mixing chamber, wherein the first emulsion comprises (i) an organic solution comprising a polymeric material and an organic solvent mixed with (ii) a first aqueous solution comprising a nucleic acid;

(c) continuously supplying a second aqueous solution to the mixing chamber, wherein the second aqueous solution comprises a surfactant;

(d) continuously emulsifying the first emulsion and the second aqueous solution in the mixing chamber to form a second emulsion, the second emulsion comprising nucleic acid, polymeric material, water, and organic solvent;

(e) continuously transferring the second emulsion from the mixing chamber to the solvent removal device; and

(f) forming ~~removing the organic solvent from the second emulsion in the solvent removal device to form~~ an aqueous suspension of nucleic acid-containing microparticles in the solvent removal device via diffusion of the organic solvent into an aqueous phase of the second emulsion;

wherein at least one of the first emulsion and the second aqueous solution further comprises a stabilizer.

2. (Original) The process of claim 1 wherein the first aqueous solution and the second aqueous solution are of essentially equal osmolarity.

3. (Original) The process of claim 2, wherein the stabilizer comprises a carbohydrate and a buffer.

4. (Original) The process of claim 3 wherein the stabilizer comprises sucrose and TRIS-EDTA.

5. (Original) The process of claim 4 wherein the stabilizer additionally comprises a lipid.

6. (Original) The process of claim 1 wherein the stabilizer comprises a lipid.

7. (Original) The process of claim 1, further comprising:

(g) providing a diafiltration apparatus;

(h) diluting the aqueous suspension with an aqueous wash solution;

(i) supplying the diluted aqueous suspension to the diafiltration apparatus; and

(j) removing an aqueous waste solution from the diluted aqueous suspension in the diafiltration apparatus, wherein the aqueous waste solution comprises at least some of the wash solution of step (h), to form in the diafiltration apparatus a purified aqueous suspension comprising nucleic acid-containing microparticles.

8. (Original) The process of claim 7, further comprising:

(k) concentrating the purified aqueous suspension in the diafiltration apparatus to form a concentrate; and

(l) transferring the concentrate into one or more vessels.

9. (Original) The process of claim 8 further comprising:

(m) lyophilizing, freeze-drying, or air-drying the concentrate in the one or more vessels, to form lyophilized, freeze-dried, or air-dried microparticles.

10. (Original) The process of claim 9 wherein the lyophilized or freeze-dried microparticles have a residual organic solvent level of less than 200 ppm.

11. (Original) The process of claim 10 wherein the lyophilized or freeze-dried microparticles have a residual organic solvent level of less than 50 ppm.

12. (Original) The process of claim 1, further comprising:

(g) contacting the aqueous suspension with a vibrating or non-vibrating fine-mesh screen;

(h) filtering the aqueous suspension through the screen to remove at least some of each of said first and second aqueous solutions and to retain the microparticles on the screen;

(i) washing the microparticles with at least one aqueous wash solution to produce washed microparticles; and

(j) drying the washed microparticles to produce dried microparticles.

13. (Original) The process of claim 12, wherein the drying step comprises lyophilizing, freeze-drying, or air-drying the washed microparticles.

14. (Original) The process of claim 12, wherein the first aqueous wash solution is sterile water-for-injection at a temperature of about 2°C to about 8°C.

15. (Original) The process of claim 12, further comprising contacting the washed microparticles with an excipient, prior to the drying step.

16. (Original) The process of claim 12, further comprising:

(k) transferring the dried microparticles into one or more vessels.

17. (Original) The process of claim 1, wherein the mixing chamber comprises a homogenizer.

18. (Currently Amended) The process of claim 1, wherein the solvent removal device is a hardening tank ~~bioreactor~~.

19. (Original) The process of claim 1, wherein the second aqueous solution is supplied to the mixing chamber at a flow rate of between 0.1 and 20 l/min.

20. (Original) The process of claim 1, wherein the organic solvent is removed from the second emulsion in the solvent removal device by evaporation.

21. (Original) The process of claim 1, wherein the organic solvent is removed from the second emulsion by heating the second emulsion in the solvent removal device to between 30°C and 55°C.

22. (Original) The process of claim 1, wherein the organic solvent is removed from the second emulsion in the solvent removal device by an extraction process.

23. (Original) The process of claim 1, wherein the removal of the organic solvent from the second emulsion in the solvent removal device is facilitated by diluting the second emulsion in the solvent removal device.

24. (Original) The process of claim 1, wherein the organic solvent is removed from the second emulsion in the solvent removal device by applying a partial vacuum to the solvent removal device.

25. (Original) The process of claim 1, wherein the organic solvent comprises dichloromethane.

26. (Original) The process of claim 9, wherein each of the steps is carried out aseptically.

27. (Original) The process of claim 7, wherein the diafiltration apparatus comprises a hollow fiber system.

28. (Original) The process of claim 7, wherein steps (i) and (j) are carried out at a temperature of between about 2°C and about 8°C.

29. (Original) The process of claim 1, wherein at least about 50% of the nucleic acid in the microparticles is in the form of circular RNA molecules or supercoiled circular DNA molecules.

30. (Original) The process of claim 7, wherein at least about 50% of the nucleic acid in the microparticles in the purified aqueous suspension is in the form of circular RNA molecules or supercoiled circular DNA molecules.

31. (Original) The process of claim 9, wherein at least about 50% of the nucleic acid in the lyophilized or freeze-dried microparticles is in the form of supercoiled circular DNA molecules.

32. (Original) The process of claim 1, wherein the average diameter of microparticles is less than about 100 microns.

33. (Original) The process of claim 31, wherein the average diameter is less than about 20 microns.

34. (Currently Amended) The process of claim 32, wherein the average diameter is between about 0.5 and about 2.5 microns~~, inclusive~~.

35. (Original) The process of claim 1, wherein the polymeric material is a synthetic, biodegradable polymer.

36. (Original) The process of claim 35, wherein the polymer is poly-lactic-*co*-glycolic acid (PLGA).

37. (Original) The process of claim 36, wherein the ratio of lactic acid to glycolic acid in the PLGA is between about 1:2 and about 4:1 by weight.

38. (Original) The process of claim 37, wherein the ratio of lactic acid to glycolic acid in the PLGA is about 1:1 by weight.

39. (Original) The process of claim 36, wherein the PLGA has an average molecular weight in the range of 6,000 to 100,000.

40. (Original) The process of claim 1, wherein the second aqueous solution further comprises polyvinyl alcohol (PVA).

41. (Original) The process of claim 40, wherein the second aqueous solution further comprises a carbohydrate.

42. (Original) The process of claim 41, wherein the carbohydrate is sucrose.

43. (Original) The process of claim 1, wherein the emulsifying step (d) is carried out at between about 2°C and about 8°C.

44. (Original) The process of claim 1, wherein the average residence time of the first emulsion and the second aqueous solution in the mixing chamber is less than about 60 seconds.

45. (Original) The process of claim 44, wherein the average residence time of the first emulsion and the second aqueous solution in the mixing chamber is less than about 1 second.

46. (Original) The process of claim 1, wherein the average residence time of the second emulsion in the solvent removal device is less than about 3 hours.

47. (Original) The process of claim 1, further comprising:

(g) providing a diafiltration apparatus;

(h) diluting the aqueous suspension with an aqueous wash solution;

(i) supplying the diluted aqueous suspension to the diafiltration apparatus;

(j) removing an aqueous waste solution from the diluted aqueous suspension in the diafiltration apparatus, wherein the aqueous waste solution comprises at least some of the wash solution of step (h), to form in the diafiltration apparatus a purified aqueous suspension comprising nucleic acid-containing microparticles;

(k) washing the purified aqueous suspension to form a suspension of washed

microparticles;

(l) concentrating the suspension of washed microparticles to form a concentrate;

(m) transferring the concentrate into one or more vessels; and

(n) lyophilizing, freeze-drying, or air-drying the concentrate in the one or more vessels, to form lyophilized, freeze-dried, or air-dried powder.

48. (New) The process of claim 1, wherein the first aqueous solution comprises sucrose.

49. (New) The process of claim 1, wherein the first aqueous solution comprises EDTA.

50. (New) The process of claim 1, wherein the first aqueous solution comprises the stabilizer.

51. (New) The process of claim 1, wherein at least about 60% of the nucleic acid in the microparticles is in the form of circular RNA molecules or supercoiled circular DNA molecules.

52. (New) The process of claim 1, wherein at least about 70% of the nucleic acid in the microparticles is in the form of circular RNA molecules or supercoiled circular DNA molecules.

53. (New) The process of claim 1, wherein at least about 80% of the nucleic acid in the microparticles is in the form of circular RNA molecules or supercoiled circular DNA molecules.

54. (New) The process of claim 1, wherein the average residence time of the first emulsion and the second aqueous solution in the mixing chamber is less than about 30 seconds.

55. (New) The process of claim 1, wherein the average residence time of the first emulsion and the second aqueous solution in the mixing chamber is less than about 10 seconds.